counter-pulsating device, with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976, or that has, on or before March 31, 2014, been found to be substantially equivalent to any external counter-pulsating device, with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976. Any other external counter-pulsating device with an intended use described in paragraph (b)(2) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[78 FR 79307, Dec. 30, 2013]

§ 870.5300 DC-defibrillator (including paddles).

(a) *Low-energy DC-defibrillator*—(1) *Identification.* A low-energy DC-defibrillator is a device that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart or to terminate other cardiac arrhythmias. This generic type of device includes low energy defibrillators with a maximum electrical output of less than 360 joules of energy that are used in pediatric defibrillation or in cardiac surgery. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body.

(2) *Classification.* Class II (performance standards).

(b) *High-energy DC-defibrillator*—(1) *Identification.* A high-energy DC-defibrillator is a device that delivers into a 50 ohm test load an electrical shock of greater than 360 joules of energy used for defibrillating the atria or ventricles of the heart or to terminate other cardiac arrhythmias. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body.

(2) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any DC-defibrillator (including paddles) described in paragraph (b)(1) of this section that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a DC-defibrillator (including paddles) described in paragraph (b)(1) of this section that was in commercial distribution before May 28, 1976. Any other DC-defibrillator (including paddles) described in paragraph (b)(1) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 61 FR 50706, Sept. 27, 1996]

§ 870.5310 Automated external defibrillator.

(a) *Identification.* An automated external defibrillator (AED) is a low-energy device with a rhythm recognition detection system that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart. An AED analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia.

(b) *Classification.* Class III (premarket approval)

(c) *Date PMA or notice of PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

[68 FR 61344, Oct. 28, 2003; 69 FR 10615, Mar. 8, 2004]

§ 870.5325 Defibrillator tester.

(a) *Identification.* A defibrillator tester is a device that is connected to the output of a defibrillator and is used to